

WHAT WE CLAIM IS:

1. A method of treatment for the prevention or amelioration of tissue damage in a subject who does not have Wilson's disease to prevent or ameliorate tissue damage, which comprises parenterally administering to said subject a therapeutically effective amount of a copper chelator in an amount ranging from about 5mg to about 1100mg.

2. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of diabetic cardiomyopathy, diabetic acute coronary syndrome, diabetic hypertensive cardiomyopathy, acute coronary syndrome associated with impaired glucose tolerance, acute coronary syndrome associated with impaired fasting glucose, hypertensive cardiomyopathy associated with impaired glucose tolerance, hypertensive cardiomyopathy associated with impaired fasting glucose, ischemic cardiomyopathy associated with impaired glucose tolerance, and ischemic cardiomyopathy associated with impaired fasting glucose.

3. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of myocardial infarction, ischemic cardiomyopathy associated with coronary heart disease, cardiomyopathy, myocarditis, idiopathic cardiomyopathy, metabolic cardiomyopathy, alcoholic cardiomyopathy, drug-induced cardiomyopathy, ischemic cardiomyopathy, and hypertensive cardiomyopathy, acute coronary syndrome not associated with any abnormality of glucose metabolism, hypertensive cardiomyopathy not associated with any abnormality of glucose metabolism, and ischemic cardiomyopathy not associated with any abnormality of glucose metabolism

4. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of one or more diseases of the vascular tree including disease states of the aorta, carotid, and of the arteries including cerebrovascular, coronary, renal, retinal, iliac, femoral, popliteal, *vasa nervorum*, arteriolar tree and capillary bed, atheromatous disorders of the major blood vessels including the aorta, the coronary arteries, the carotid arteries, the cerebrovascular arteries, the renal arteries, the iliac arteries, the femoral arteries, and the popliteal arteries.

5. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of cardiac structure damage.

6. The method of claim 5 wherein said cardiac structure damage is selected from the group consisting of atrophy, loss of myocytes, expansion of the extracellular space, and increased deposition of extracellular matrix.

7. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of coronary artery structure damage.

8. The method of claim 7 wherein said coronary artery structure damage is selected from the group consisting of media layer damage and intima layer damage.

9. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder comprising the plaque rupture of atheromatous lesions of one or more major blood vessels.

10. The method of claim 9 wherein said major blood vessels are selected from the group consisting of the aorta, the coronary arteries, the carotid arteries, the cerebrovascular arteries, the renal arteries, the iliac arteries, the femoral arteries and the popliteal arteries,

11. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder selected from the group consisting of systolic dysfunction, diastolic dysfunction, aberrant contractility, aberrant recoil characteristics, and aberrant ejection fraction.

12. The method of claim 1 wherein said copper chelator is parenterally administered to said subject for treatment of a disease, condition or disorder comprising microvascular disease.

13. The method of claim 12 wherein said microvascular disease comprises a disorder of one or more of vessels selected from the group consisting of retinal arterioles, glomerular arterioles, *vasa nervorum*, cardiac arterioles, and associated capillary beds of the eye, the kidney, the heart, the central nervous system, and the peripheral nervous system.

14. The method of claim 1 wherein said copper chelator is administered in a single dose or in divided doses.

15. The method of claim 1 wherein said about 5mg to about 1100mg of said copper chelator is administered per day in a single dose or in divided doses.

16. The method of claim 1 wherein said copper chelator is trientine.

17. The method of claim 1 wherein said copper chelator is a trientine salt.

18. The method of claim 1 wherein said copper chelator is a trientine derivative.

19. The method of claim 1 wherein said copper chelator is a trientine analogue.

20. The method of claim 1 wherein said copper chelator is a trientine prodrug.

21. The method of any of claims 1-20 wherein said administration is by a route selected from the group consisting of transdermal delivery, topical application, suppository delivery, transmucosal delivery, inhalation, insufflation, buccal delivery, sublingual delivery, and ophthalmic delivery.

22. The method of any of claims 1-20 wherein said administration is by injection.

23. The method of claim 22 wherein said injection is by subcutaneous injection, subdermal injection, intramuscular injection, depot administration, and intravenous injection.

24. The method of claim 23 wherein said intravenous injection is a bolus injection or an by intravenous drip injection.

25. The method of any of claims 1-20 wherein said administration is by an infusion device.

26. The method of claim 25 wherein said infusion device is a passive or active implantable infusion device.

27. A delivery dosage unit or dosage formulation comprising a therapeutically effective amount of a copper chelator and pharmaceutically acceptable delivery vehicle, said delivery dosage unit being capable of delivery into a human subject of more than 10% w/w of said copper chelator upon administration to said human.

28. A unit of claim 27 wherein the dosage unit is oral and said more than 10%^{w/w} delivery is of that quantity orally taken that moves from the gut into the systemic circulation.

29. A dosage unit of claim 28 wherein copper chelator is a trientine active agent.

30. A dosage unit as claimed in claim 29 wherein the copper chelator is trientine.

31. A dosage unit as claimed in claim 29 wherein the preceding claims wherein the copper chelator is a pharmaceutically acceptable salt of trientine

32. A dosage unit as claimed in claim 29 wherein copper chelator is a prodrug of trientine.

33. A dosage unit as claimed in claim 29 wherein the copper chelator is an analog of trientine.

34. A dosage unit of any of claims 28 to 33 wherein the delivery vehicle is, contains or is associated with at least one delivery agent to enhance entry to the systemic circulation from the gut of the human subject.

35. A unit of claim 34 wherein the at least one delivery agent is one or more synthetic and/or natural polymer.

36. A unit of claim 35 wherein the at least one delivery agent is one or more bioadhesive polymer.

37. A unit of claim 35 wherein the at least one delivery agent is one or more passive diffusion agent.

38. A unit of claim 35 wherein the at least one delivery agent is one or more active transport agent.

39. A unit of claim 35 wherein the at least one delivery agent is one or more facilitated active transport agent.

40. A unit of any one of claims 28 to 39 wherein the copper chelator is admixed with the delivery vehicle.

41. A unit of any one of claims 28 to 40 that is enteric coated, enteric embedded and/or enteric contained.

42. A unit of any one of claims 28 to 41 being a slow release form.

43. A unit of claim 42 wherein unit has an enteric coated slow release core.

44. A unit of claim 42 or 43 that involves imcorencapsulation.

45. A unit of any one of claims 28 to 44 wherein more than 50% of the therapeutically acceptable chelator in less than 12 hours is dissolved from the unit into the gastro intestinal tract.

46. A unit of any one of claims 28 to 45 which is a repeat action dosage form having provision for staged release.

47. A unit of any one of claims 28 to 46 wherein the amount of copper chelator in the dosage unit is less than 300mg.

48. A unit of claim 47 wherein the amount of copper chelator in the dosage unit is less than 250 mg.

49. A unit of claim 48 wherein the amount of copper chelator in the dosage unit is less than 240 mg.

50. A unit of claim 49 wherein the amount of copper chelator in the dosage unit is from 120 to 140 mg.

51. A unit of any one of claims 28 to 50 wherein more than 15%^{w/w} of the copper chelator is capable of being delivered from the gut.

52. A unit of claim 51 wherein more than 20%^{w/w} of the copper chelator is deliverable.

53. A unit of claim 52 wherein more than 25%^{w/w} of the copper chelator is deliverable.

54. A unit of claim 53 wherein more than 30%^{w/w} of the copper chelator is deliverable.

55. A unit or formulation of claim 27 that is parenteral.

56. A dosage unit or formulation of claim 55 wherein the therapeutically acceptable copper chelator is a trientine active agent.

57. A dosage unit or formulation as claimed in claim 56 wherein the therapeutically acceptable copper chelator is trientine.

58. A dosage unit or formulation as claimed in claim 56 wherein the therapeutically acceptable copper chelator is a salt of trientine.

59. A dosage unit or formulation as claimed in claim 56 wherein the therapeutically acceptable copper chelator is a prodrug of trientine.

60. A dosage unit or formulation as claimed in claim 56 wherein the therapeutically acceptable copper chelator is an analog of trientine.

61. A unit of any one of claims 55 to 60 wherein the dosage unit is transdermal.

62. A dosage unit of claim 61 wherein it is in the form of a transdermal patch, pad, wrap or bandage capable of being adhered or otherwise associated with the skin of a subject.

63. A formulation of any one of claims 55 to 60 that is a topical administration formulation.

64. A dosage unit or formulation of claim 61, 62 or 63 wherein at least 20% of the copper chelator amount is deliverable into the systemic circulation.

65. A unit of claim 55 wherein the dosage unit is sublingual.

66. A dosage unit of claim 65 wherein at least 20% of the copper chelator amount is deliverable into the systemic circulation.

67. A unit of claim 27 wherein the dosage unit is a suppository.

68. A dosage unit of claim 67 wherein at least 20% of the copper chelator amount is deliverable into the systemic circulation.

69. A dosage formulation of claim 55 that is injectable.

70. A formulation of claim 69 wherein at least 50%^{w/w} of the copper chelator is deliverable into the systemic circulation.

71. A formulation of claim 69 or 70 that is intravenous.

72. A formulation of claim 69 or 70 that is subcutaneous.

73. A formulation of claim 69 or 70 that is intramuscular.

74. A dosage unit or formulation of claim 51 that is depot implantable or depot injectable.

75. A unit or formulation of claim 74 wherein at least 20%^{w/w} of the copper chelator present is deliverable into the systemic circulation.

76. A unit or formulation of claim 28 that is deliverable from an inhalation device.

77. A unit or formulation of claim 76 wherein at least 20%^{w/w} of the copper chelator present is deliverable into the systemic circulation.

78. A formulation of claim 51, which is of a formulation deliverable via the eye.

79. A dosage unit or dosage formulation of any one of claims 27 to 78 for use in a method of any one of claims 1 to 26.

80. A dosage unit or dosage formulation of any one of claims 27 to 79 when packed with a label or instructions for use thereof in the treatment of a disease, condition or disorder of any one of claims 1 to 26.

81. A dosage unit or dosage formulation of claim 80 wherein a once a day administration is instructed.

82. The use of a copper chelator and other material or materials in the manufacture of a dosage unit or dosage formulation of any one of the claims 27 to 81.

83. The use of claim 82 when for use in a method of treatment as claimed in any one of claims 1 to 26.